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EXAMINER	
ARTMAN, THOMAS R	

ART UNIT	PAPER NUMBER
2882	

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/037,477	TAKAI ET AL.	
	Examiner	Art Unit	
	Thomas R. Artman	2882	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-20,22-28,34 and 37-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,12-20,22-28,34 and 37-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 July 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/5/02;9/3/02;3/10/03; 2/22/04; 1/19/05*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

The information disclosure statements (IDS) submitted on August 15th, 2002, September 3rd, 2002, March 10th, 2003, March 22nd, 2004, and the eIDS submitted on January 21st, 2005, are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Objections

Claims 1 and 10 are objected to because of the following: antecedent basis is lacking for the term "the at least one marker" in line 2 of claim 1 and line 3 of claim 10. The examiner suggests replacing "the" with "a". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Both claims recite the limitation "the at least one marker" in lines 2 and 4, respectively. There is insufficient antecedent basis for this limitation in the claims. The limitation introducing a marker into the claimed process was deleted from parent claim 25 in the amendment filed on

March 31st, 2005, thus removing the antecedence of the limitation and resulting in ambiguity. The structural and functional relationships between the marker of claims 22 and 23 and the remaining limitations of the radiation process are unclear as a result.

Election/Restrictions

Upon further review, the examiner hereby withdraws the restriction requirement made in the previous Office action, dated July 13th, 2005. All pending claims are being examined.

Allowable Subject Matter

Upon further review, the examiner hereby withdraws the indication of allowable subject matter of independent claim 12. The claims are currently rejected over Kunieda et al. below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7, 9, 10, 12-15 and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Kunieda (US 6,307,914 B1).

Regarding claims 1 and 10, Kunieda discloses an apparatus and method for irradiating a target (Figs. 1, 18, 19 and 20), including:

a) establishing a relationship between at least one marker 17 relative to the target (tumor, not referenced in the figures) by measuring a relative position between the at least one marker and the target (col.12, lines 24-42),

b) generating an image signal of the at least one marker,

c) generating a tracking signal in response to the image signal, and

d) adjusting a radiation beam in response to the tracking signal for tracking the target (col.3, lines 14-37).

With respect to claim 2, Kunieda further discloses the practice of generating an X-ray image of the marker, and the step of generating a tracking signal includes generating the tracking signal to track a movement of the target (col.3, lines 14-37).

With respect to claim 3, Kunieda further discloses the practice of generating the image signal regarding an anatomy of a patient having a tumor as the target (col.3, lines 14-37).

With respect to claims 4 and 5, Kunieda further discloses the practice of

a) illuminating the target and the area near the target with first and second image beams, where the beams are not parallel to each other, and

b) detecting first and second images, respectively, of the marker (col.3, lines 14-37).

With respect to claim 7, Kunieda further discloses the practice of adjusting the radiation beam using a first multileaf collimator 15a (col.4, lines 6-11; col.16, lines 13-37).

With respect to claim 9, Kunieda further discloses the practice of temporarily shutting off the beam in response to the tracking signal having a value indicating the target being outside an area (col.9, lines 20-28; col.12, lines 47-63).

Regarding claim 12, Kunieda discloses an apparatus for irradiating a target (Figs. 1, 18, 19 and 20), including:

a) a platform 20 for supporting an object having a marker 17 indicating a position of the target,

b) a radiation source generating a radiation beam 16 toward the platform,

c) a beam adjuster 15a between the radiation source and the platform, where the adjuster is a multileaf collimator,

d) a first image detector 21d,e generating a first image signal of the marker,

e) a control module (Fig.20) coupled to the image detector and to the beam adjuster, where the control module generates a beam adjustment signal for controlling the first multileaf collimator to track a movement of the target in response to the first image signal (col.4, lines 6-11; col.16, lines 13-37), and

f) the control module is further coupled to the radiation source, where the control module generates a control signal to switch off the radiation source in conjunction with generating the beam adjustment signal (col.9, lines 20-28; col.12, lines 47-63).

With respect to claim 13, Kunieda further discloses that the control module is coupled to the platform and generates a control signal to move the platform in response to the first image signal (Fig.19; col.3, line 66 through col.4, line 5; col.15, line 57 through col.16, line 11).

With respect to claim 14, Kunieda further discloses that the first image detector is a video camera (Fig.24) or an X-ray imager (Figs. 1, 19 and 20).

With respsect to claim 15, Kunieda further discloses that a gantry houses the radiation source and the beam adjuster (Fig.20).

With respect to claim 17, Kunieda further discloses a first image beam source 21a,b generating a first image beam toward the platform 20, where the first image detector 21d,e generates a first image signal by detecting the first image beam (Figs.19-20).

With respect to claim 18, Kunieda further discloses a second image beam source 22a,b that generates a second image beam toward the platform in a direction that is not parallel to the first image beam, and a second image detector 22d,e coupled to the control module, where the second image detector generates a second image signal by detecting the second image beam (Figs.19 and 20).

With respect to claim 19, Kunieda further discloses that the first image adjuster is a first multileaf collimator, which as is known in the art, has first and second rows of movable leaves opposite to each other.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunieda, as applied above against claims 1 and 12, respectively, in view of Hughes (US 6,600,810 B1).

With respect to both claims, Kunieda does not disclose the practice of using a second multileaf collimator.

Hughes teaches the practice of using two multileaf collimators, oriented such that the leaves of the first collimator are not parallel to the second collimator, in order to more precisely control the beam shape (Figs.4 and 5; see at least Title and Abstract). In this way, greater conformity of the beam to the target shape is realized, thus reducing the amount of radiation harming surrounding healthy tissues.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kunieda to use a second multileaf collimator in order to improve beam conformity to the tumor shape and thus reduce the risk of damage to surrounding tissues, as taught by Hughes.

Claims 6, 22-26 and 28 are rejected under 35 U.S.C. 103(s) as being obvious over Kunieda in view of Kanematsu (US 6,385,288 B1).

Regarding claim 25, Kunieda discloses a radiation process (Figs.10, 19 and 20), including:

a) generating a first image signal of an area (from image detector 21a,b),

b) generating a tracking signal in response to the first image signal to track a movement of a portion of a target, where the target is located within a patient, and

c) adjusting a first multileaf collimator 15a in response to the tracking signal to adjust a radiation beam projected onto the patient (col.3, lines 14-37).

Further regarding claim 25 and with respect to claim 6, Kunieda does not specifically disclose the practice of superimposing the tracking signal on the radiation treatment plan, thus generating a beam adjustment signal for adjusting the shape of the beam. However, it is clear from col.16, lines 25-35, that the multileaf collimator is used to dynamically follow the target by changing where the beam is emitted from the collimator as a real time adjustment.

Kanematsu specifically teaches the practice, where a first image signal of the target area is generated, the resulting tracking signal is superimposed on the treatment plan, and the collimator 8 is adjusted in order to change the shape of the beam (radiation field) in order to conform the beam cross section to the deformation of the target during treatment (Fig.5 and col.10, lines 10-29; col.12, line 10 through col.13, line 15). In this way, the target is more accurately irradiated and the surrounding tissues are more accurately avoided.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for the device of Kunieda to superimpose the tracking signal on the radiation treatment

plan in order to change the shape of the radiation beam in order to realize a more efficient and accurate therapy process, as taught by Kanematsu.

With respect to claim 22, Kunieda implants a marker into the patient (col.3, lines 14-20).

With respect to claims 23 and 24, Kunieda further discloses the practice of

a) illuminating the target and the area near the target with first and second image beams, where the beams are not parallel to each other, and

b) detecting first and second images, respectively, of the marker and generating an image signal (col.3, lines 14-37).

With respect to claim 26, both Kunieda and Kunematsu teach the practice of moving a platform supporting the patient to reposition the patient in response to the tracking signal (Fig.19; col.3, line 66 through col.4, line 5; col.15, line 57 through col.16, line 11 of Kunieda; Fig.4 of Kunematsu).

With respect to claim 28, Kunieda further teaches the practice of generating a control signal to switch off the radiation source in response to the tracking signal (col.9, lines 20-28; col.12, lines 47-63).

Claim 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunieda and Kunematsu, as applied to claim 25 above, in view of Depp (US 5,427,097).

Kunieda does not specifically disclose the practice of moving the source of the radiation beam in order to adjust a projection direction of the radiation beam onto the patient in response to the tracking signal.

Depp specifically teaches such a practice (Fig.1, col.5, lines 10-34), where the gantry that houses the radiation source is moved in response to a tracking signal based upon image data from the tracking sources and detectors in order to keep the radiation beam on target. It is preferable to keep the patient relatively stationary for safety and precautionary reasons and move the gantry (col.5, lines 32-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kunieda to move the radiation source in response to the tracking signal in order to keep the radiation signal on track and to reduce potential harm to the patient, as taught by Depp.

Claims 16, 34, 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kunieda in view of Depp.

With respect to claim 16, Kunieda, as applied to claim 15 above, does not specifically disclose the additional limitation of the practice of moving the source of the radiation beam in order to adjust a projection direction of the radiation beam onto the patient in response to the tracking signal.

Depp specifically teaches such a practice (Fig.1, col.5, lines 10-34), where the gantry that houses the radiation source is moved in response to a tracking signal based upon image data from the tracking sources and detectors in order to keep the radiation beam on target. It is preferable to keep the patient relatively stationary for safety and precautionary reasons and move the gantry (col.5, lines 32-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kunieda to move the radiation source in response to the tracking signal in order to keep the radiation signal on track and to reduce potential harm to the patient, as taught by Depp.

Regarding claim 34, Kunieda discloses a method for irradiating a target (Figs. 1, 18, 19 and 20), including:

a) establishing a relationship between at least one marker 17 relative to the target (tumor, not referenced in the figures) by measuring a relative position between the at least one marker and the target (col.12, lines 24-42),

b) generating an image signal of the at least one marker,

c) generating a tracking signal in response to the image signal, and

d) adjusting a radiation beam in response to the tracking signal for tracking the target (col.3, lines 14-37).

Kunieda does not specifically disclose the use of internal anatomy of a patient as a marker. Kunieda uses an artificial, implanted marker 17.

Depp specifically teaches the practice of using either existing anatomy, such as a bone, or an implanted marker, depending upon the proximity between the internal anatomy and the target

(col.1, lines 50-65). As is known to one skilled in the art, the use of existing anatomy within the patient reduces the need for the invasive surgery of implanting artificial markers, which is not time or cost effective and increases the chance for the patient to become infected in some way.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kunieda to use internal anatomy for the convenience, safety and economics over that of implanting an artificial marker, as taught by Depp.

With respect to claim 40, Kunieda further discloses that the image signal is generated using a camera 21e.

With respect to claim 41, Kunieda further discloses the practice of adjusting the radiation beam using a multileaf collimator 15a (col.4, lines 6-11; col.16, lines 13-37).

Claims 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kanematsu in view of Depp.

Regarding claim 37, Kanematsu discloses a process for irradiating a target (Figs.1, 4 and 5), including:

a) collecting a plurality of images in a same physiological cycle, where the plurality of images provide an indication of a location of the target,

b) create a treatment plan based at least in part on the plurality of images collected at the plurality of phases in the cycle, and

c) delivering a radiation beam to the animal body according to the treatment plan (col.11, lines 35-57).

Further regarding claim 37, and with respect to claims 38 and 39, Kanematsu does not specifically disclose that the images provide an indication of a location of a target relative to an internal marker, either anatomical or implanted. Kanematsu relies on the target itself.

Depp specifically teaches the practice of using either internal anatomy or implanted markers in order to determine the location of a target via automated tracking systems for radiation therapy similar to that of Kanematsu (col.1, lines 50-65). As is known in the art, the use of a marker, such as an implanted marker or nearby bones, provide improved detection reliability since tumors and other diseased tissues are tissues that are similar in attenuation to benign surrounding tissues. A marker provides sharper contrast, particularly for automated tracking, such that movement is more easily detected.

It would have been obvious to one of ordinary skill in the art at the time the invention was made for Kanematsu to use either an implanted marker or internal anatomy in order to more accurately detect and measure motion of a target region of a patient as taught by Depp.

Response to Arguments

Applicant's arguments with respect to claims 1, 10, 12, 25, 34 and 37 have been considered but are moot in view of the new ground(s) of rejection. However, some rejections are the same and relevant arguments will be addressed.

Regarding claims 1 and 10, Applicants assert that Kunieda puts the marker at the same place as the target, and therefore does not perform the claimed function of measuring a relative position between the at least one marker and the target. The examiner respectfully disagrees.

The passage of Kunieda cited above is sufficient on the matter (see col.12, lines 24-45, particularly lines 38-40). Applicants point to Fig.7A to prove the assertion that the implanted marker and the target are occupying the same space. This is an assumption that cannot be made. The passage above does not refer to any particular figure, and Fig.7A shows only a top view. Fig.9A shows a side view where the tumor marker is not exactly at the tumor position. Furthermore, in col.3, lines 14-17, the tumor marker is "placed in the vicinity of the tumor," which means it is nearby the tumor, not exactly at the tumor itself.

Furthermore, in other embodiments, the marker is external, where the tumor is internal (Fig.24). Fundamentally, as is known to one skilled in the art, the position of the marker 17 with respect to the tumor must be known since the objective of the invention is to radiate the tumor, not the marker, where the marker is used solely to quickly and accurately determine the position of the tumor. It is difficult and time-consuming, particularly from the standpoint of automated tracking, to identify the tumor itself in the X-ray images. The spatial relationship between a tumor marker and the tumor is always known, or the whole procedure is useless and, in fact, dangerous to the patient.

Regarding claim 12, upon further consideration, it appears that the claims read upon Kunieda as stated above. As a result, the indication of allowable subject matter is withdrawn. The examiner cannot ascertain from the record what was considered to be novel or unobvious in claim 12.

Regarding claim 25, the examiner has withdrawn the restriction requirement, and thus the rejection above has been made on the grounds of Kunieda and Kunematsu, which are different than previously used to reject the claim.

Regarding claim 34, the examiner agrees with Applicants' arguments; however, new grounds of rejection have been found in view of Depp and are applied above.

Regarding claim 37, the frame rate of Kunieda, 30 Hz, is more than sufficient to acquire a plurality of images of a plurality of phases of a given physiological cycle. However, Kunieda does not disclose the practice of creating a treatment plan based upon these images. Therefore, the grounds of rejection for claim 37 have been changed.

Finally, the 35 USC 112 1st paragraph rejection of claim 37 has been withdrawn. It appears that there is sufficient disclosure in the specification, particularly in paragraph 0036, to enable one of ordinary skill in the art to perform the claimed function.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Norman (US 5,008,907) teaches the practice of imaging the radiation beam and the heavily attenuated portions in order to evaluate the accuracy of the therapy, to develop a treatment plan and to track the tumor with respect to the treatment beam.

Adler (US 6,778,850 B1) teaches an external marker approach to patient positioning and tracking during therapy, where Adler (US 5,207,223) teaches the tracking internal markers.

Mostafavi (US 6,937,696 B1 and US 6,621,889 B1) teach radiation therapy treatment planning and execution while measuring and predicting target motion due to physiological cycles and repositioning the patient/beam accordingly.

Hsieh (US 6,480,560 B2), Rasche (US 6,865,248 B1) and Bulkes (US 6,721,386 B2) teach the practice of physiological imaging procedures using CT.

Schweikard (US 6,144,875) teaches the practice of correlating external and internal marker positions in order to track a tumor during therapy.

Ein-Gal (US 6,526,123 B2 and US 6,266,393 B1) teach the practice of using two non-parallel multileaf collimators in therapy systems.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas R. Artman whose telephone number is (571) 272-2485. The examiner can normally be reached on 9am - 5:30pm Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ed Glick can be reached on (571) 272-2490. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Thomas R. Artman
Patent Examiner

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SUPERVISORY PATENT EXAMINER